Remarks

Reconsideration is respectfully requested in light of the foregoing amendment and the remarks that follow.

Claims 36-37, 39-43, 45-52 and 54-55 are pending in this application. Claims 38, 44 and 53 have been cancelled. Claims 36, 41 and 48 have been amended to include, respectively, the subject matter of cancelled claims 38, 44 and 53.

First Rejection under § 103

Claims 36-40, 42-46, and 48-54 are rejected under 35 U.S.C. § 103(a) as obvious over Ukai et al., U.S. Patent No. 6,576,677. Applicant respectfully traverses the rejection.

Ukai et al. teach the use of polyvinylpyrrolidone and/or copolyvidone to alleviate an unpleasant taste of a basic medicament. Ukai et al. additionally teaches the beneficial use of an antioxidant, a colorant or flavorant containing a sulfurous or sulfuric acid group. See col. 1 at lines 40-60. The basic medicament having the unpleasant taste, e.g. donepezil hydrochloride, has a positive charge under acidic conditions. See col. 2 at lines 5-19. The polyvinylpyrolidone and/or copolyvidone is taught to reduce the unpleasant taste by trapping the proton with two pyrrolidone groups. See col. 2 at lines 20-26. The Ukai et al formulations have an acidic pH (3-7). See col. 3 at lines 1-9 and Example 2 (pH of 5). Test 1 shows 700 mg of polyvinylpyrrolidone per 5 mg of donepezil hydrochloride (more than a 100 fold difference). Test 2 shows 700 mg., 500 mg. and 100 mg. of polyvinylpyrrolidone per 5 mg donepezil hydrochloride (more than a 20 fold difference). (Cf. the example in the instant specification where the 50 mg. of polyvinylpyrrolidone is employed with 5 mg. of donepezil hydrochloride (10 fold difference).

At col. 5, lines 1-7, Ukai et al. teach that the masking effects are heightened with increased amounts of polyvinylpyrolidone. This is clearly shown in Table 2. (The passage may be confusing as written.) This would suggest optimization would require increased amounts of polyvinylpyrolidone rather than the lower amounts required by the claims.

Further, as a point of distinction Applicant employs a formulation having a basic pH range. The claim are now so limited. (Claims 36, 41 and 48 have been amended to include, respectively, the subject matter of cancelled claims 38, 44 and 53 (basic pH range).)

The medicament species addressed by Applicant is in a different form than Ukai et al. The conditions, parameters to be optimized here are distinct from those taught by Ukai et al.. More than polyvinylpyrolidone amounts are at issue. Accordingly, Applicant respectfully requests that the rejection under 35 U.S.C. § 103 be withdrawn since a proper prima facie case has not been established.

Second Rejection under § 103

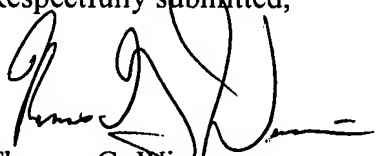
Claims 41, 47, and 55 are rejected under 35 U.S.C. § 103(a) as obvious over Ukai in view of Sugimoto et al., U.S. Patent No. 4,895,841.

In view claims 36-40, 42-46, and 48-54 are unobvious over Ukai, claims 41, 47, and 55 would also be unobvious over Ukai in view of Sugimoto, as Sugimoto does not cure the deficiencies of Ukai. In view thereof, Applicant respectfully requests that the rejection under 35 U.S.C. § 103 be withdrawn.

Conclusion

An early and favorable reconsideration and allowance of pending claims 36-37, 39-43, 45-52 and 54-55 is respectfully requested.

Respectfully submitted,



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